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Atty Dkt. No.: 10031033-1 USSN: 10/828,892

REMARKS

Claim 1 is amended. Support for this amendment is found in page 11, line 21 to page 12, line 2. No new matter is added.

In view of the following remarks, the Examiner is requested to allow Claims 1-9 and 26-29, the only claims pending and under examination in this application.

Claim Rejections - 35 U.S.C. § 102

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bao et al. (US Publication No. 2001/0018183).

According to the M.P.E.P., a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. § 2131.

Claim 1 is directed to an array that includes at least one chromosome structural region *oligonucleotide* feature, where the feature contains oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

The Applicants submit that Bao fails to explicitly disclose an array containing oligonucleotides that specifically bind to a structural region of a single chromosome and do not specifically bind to structural regions on other chromosomes. As such, the Applicants submit that Bao fails to disclose each and every element of the rejected claims, and this rejection should be withdrawn.

Claims 1, 2 and 7-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pinkel et al. (US Publication No. 2002/0192698).

Claim 1 is directed to an array that includes at least one chromosome structural region *oligonucleotide* feature, where the feature contains oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian

cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

The Office asserts that Pinkel anticipates the rejected claims because Pinkel discloses:

[0059] The choice of genomic, cDNA or a mixture of target elements can vary with the tissue and analysis sought. For example, cDNA target elements are advantageous because the effect of repeat sequences present in some genomic DNAs is decreased and more precise detection of expressed genes is possible. Genomic DNA target elements are advantageous because the higher complexities can produce greater signal. A mixture of genomic DNA and cDNA target elements can also be used to provide more detailed genomic and expression analysis.

However, a review of the cited passage reveals that Pinkel fails to disclose an oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

As such Pinkel fails to disclose the array recited in the rejected claims.

Furthermore, the Applicants additionally note that Pinkel fails to specifically disclose any type of "chromosome structural region" probe on an array. To the extent that Pinkel discloses a probe for the detection of a chromosomal structural region (e.g., a centromere), that probe is not an oligonucleotide probe and is not part of an array. See paragraph 56.

In view of the foregoing discussion, the Applicants submit that Pinkel fails to disclose each and every element of the rejected claims. As such, the Applicants submit that Pinkel does not anticipate the rejected claims, and this rejection should be withdrawn

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brennan (USPN 5,474,796).

The rejected claims are directed to an array that includes at least one chromosome structural region oligonucleotide feature, where the feature contains oligonucleotide that specifically binds to a structural region of a single chromosome

of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

The Office asserts that Brennan anticipates the rejected claims because Brennan allegedly discloses an array that contains every possible permutation of 10mer oligonucleotides. See column 9, lines 48 to 54.

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Since Brennan makes no mention of chromosome structural regions, this rejection is based on a theory of inherency. The MPEP at § 2112 provides very clear guidance for establishing such rejections: "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis in the original). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing may result from a given set of circumstances is also not sufficient.2

Since it is far from certain that Brennan's 10-mer oligonucleotides can specifically detect any region of a genome, much less structural regions of a single chromosome of a mammalian cell, Brennan fails to anticipate the claims using a theory of inherency.

In view of the foregoing discussion, this rejection may be withdrawn.

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fodor et al. (USPN 6,582,908).

Since Fodor makes no mention of chromosome structural regions, this rejection is also based on a theory of inherency. The MPEP at § 2112 provides very

¹ MPEP at § 2112, citing In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

² MPEP at § 2112 "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

clear guidance for establishing such rejections: "The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis in the original). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing *may* result from a given set of circumstances is also not sufficient.

Since it is far from certain that Fodor's oligonucleotides can specifically detect any region of a genome, much less structural regions of a single chromosome of a mammalian cell, Fodor fails to anticipate the claims using a theory of inherency.

Further, as explained by the Court in *Metabolite Labs*. "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category." Rather, the prior art reference must be examined to see if a disclosure of the claimed species has actually been made or whether the prior art reference merely invites further experimentation to find the species. See the M.P.E.P. § 2112.

Therefore, because Fodor does not actually teach an array that includes at least one chromosome structural region oligonucleotide feature, it fails to anticipate the rejected claims. Consequently, the Applicants respectfully request that this 35 U.S.C. § 102(b) rejection of Claims 1-9 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 26, 27 and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bao et al. in view of Ahern (The Scientist (1995) 9(15):20)).

³ MPEP at § 2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

⁴ MPEP at § 2112 "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 26, 27 and 29 ultimately depend from Claim 1 and thus requires an array containing an oligonucleotide feature, where the feature contains oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

As noted above, Bao is deficient for not providing array containing such an oligonucleotide feature. Ahem is cited to provide a kit.

Since Ahern's kit fails to fill Bao's deficiency, the combination of Bao and Ahern fail to teach or suggest an element of the rejected claims.

In view of the foregoing discussion, the Applicants submit that a *prima facie* case of obviousness has not been established, and this rejection may be withdrawn.

Claims 26-29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pinkel et al. in view of Ahern.

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 26, 27 and 29 ultimately depend from Claim 1 and thus require an array containing a chromosomal structural region oligonucleotide feature where the feature contains oligonucleotide that specifically binds to a structural region of a

single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

As discussed above, Pinkel is deficient because Pinkel does not teach or reasonably suggest such a feature. Ahern is cited to provide a kit.

Since Ahern's kit fails to fill Pinkel's deficiency, the combination of Pinkel and Ahern fail to teach or suggest an element of the rejected claims.

In view of the foregoing discussion, the Applicants submit that a *prima facie* case of obviousness has not been established, and this rejection may be withdrawn.

Claims 26, 27 and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Brennan in view of Ahern.

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Claims 26, 27 and 29 ultimately depend from Claim 1 and thus require an array containing an oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

Fodor's disclosure is deficient in that it fails to inherently disclose such an oligonucleotide.

Ahern's kit fails to fill Fodor's deficiency, the combination of Fodor and Ahern fail to teach or suggest an element of the rejected claims.

As such, this rejection may be withdrawn.

Claims 26, 27 and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fodor et al. in view of Ahern.

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or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 26, 27 and 29 ultimately depend from Claim 1 and thus require an array containing an oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions on other chromosomes of the mammalian cell.

Fodor's disclosure is deficient in that it fails to inherently disclose such an oligonucleotide.

Ahern's kit fails to fill Fodor's deficiency, the combination of Fodor and Ahern fail to teach or suggest an element of the rejected claims.

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CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Mike Beck at (408) 553-3864.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10031033-1.

Respectfully submitted,

Date: February 27, 2007

James S. Keddie Registration No. 48,920

AGILENT TECHNOLOGIES, INC. Legal Department, DL429 Intellectual Property Administration P.O. Box 7599 Loveland, CO 80537-0599

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